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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,080	10/28/2004	Weijian Feng	CH001-96990	5868

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EXAMINER	
PAK, JOHN D	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 10/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/500,080	FENG, WEIJIAN	
	Examiner	Art Unit	
	JOHN PAK	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-12 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-12 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

At the outset, an observation is in order concerning the claims that are under consideration. The Examiner notes three claim sets that have been filed in this application. The first is the one originally filed on 6/23/2004. There were 14 claims there. The second set of claims appears to have been filed on 10/28/2004, and it is reproduced below --

Weijian Feng Atty. Docket No.: 37690-96990

I CLAIM:

[C1] The use of hydrochloric acid for the manufacture of a medicament for the curative treatment of tumors.

[C2] The use of hydrochloric acid according to claim 1, wherein the tumors are malignant tumors.

[C3] The use of hydrochloric acid according to claim 2, wherein the tumors are carcinomas of the liver, lungs, kidney, breast, or the metastatic carcinomas thereof, such as metastatic carcinomas of the brain, and adrenal gland.

[C4] The use of hydrochloric acid according to claim 1, wherein the tumors are benign tumors.

[C5] The use of hydrochloric acid for the manufacture of an analgesic for relieving cancerous pain.

[C6] The use of hydrochloric acid according to any one of claim 1-5 wherein the concentrations of hydrochloric acid is about 1.8% to 36 wt%.

[C7] The use of hydrochloric acid according to claim 6 wherein the concentrations of hydrochloric acid is about 18 wt%.

[C8] The use of hydrochloric acid according to claim 7, wherein the dose of hydrochloric acid is about 0.05 ~ 5 ml.

The third set of claims also appears to have been filed on 10/28/2004 and it too is reproduced below --

Serial No. 10/500,080 -3- Atty Docket No. 37690-96990

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims

[C1] (original) The use of hydrochloric acid for the manufacture of a medicament for the curative treatment of tumors.

[C2] (original) The use of hydrochloric acid according to claim 1, wherein the tumors are malignant tumors.

[C3] (original) The use of hydrochloric acid according to claim 2, wherein the tumors are carcinomas of the liver, lungs, kidney, breast, or the metastatic carcinomas thereof, such as metastatic carcinomas of the brain, and adrenal gland.

[C4] (original) The use of hydrochloric acid according to claim 1, wherein the tumors are benign tumors.

[C5] (original) The use of hydrochloric acid for the manufacture of an analgesic for relieving cancerous pain.

[C6] (currently amended) The use of hydrochloric acid according to ~~any one of~~ claim 1-5 wherein the concentrations of hydrochloric acid is about 1.8% to 36 wt%.

[C7] (original) The use of hydrochloric acid according to claim 6 wherein the concentrations of hydrochloric acid is about 18 wt%.

[C8] (original) The use of hydrochloric acid according to claim 7, wherein the dose of hydrochloric acid is about 0.05 – 5 ml.

[C9] (new) The use of hydrochloric acid according to claim 2, wherein the concentrations of hydrochloric acid is about 1.8% to 36 wt%.

[C10] (new) The use of hydrochloric acid according to claim 3, wherein the concentrations of hydrochloric acid is about 1.8% to 36 wt%.

[C11] (new) The use of hydrochloric acid according to claim 4, wherein the concentrations of hydrochloric acid is about 1.8% to 36 wt%.

[C12] (new) The use of hydrochloric acid according to claim 5, wherein the concentrations of hydrochloric acid is about 1.8% to 36 wt%.

The upshot of these three sets of claims is a confusing state of what claims are intended to be examined. Contributing to this confusing state is applicant's failure to use the original 6/23/2004 claims as the base to show markings and appropriate claim identifiers. For the purpose of this examination, the Examiner will use the **claim set reproduced immediately above on this page**, which was filed on 10/28/2004 and consists of claims 1-12. Reason for this determination is applicant's contemporaneous comment of 10/28/2004, which is reproduced below --

REMARKS

Priority data is added on page 1 of the specification. Claim 5 is amended to remove the multiple dependency and is rewritten to single dependent claims (new claims 9-12). No new matter is added by these amendments.

As shown above, applicant stated that a multiple dependency problem was removed by the amendment of 10/28/2004, which is the last amendment of record in this case. Since there is only one claim set where a multiple dependency was removed, that is the claim set which will be examined herein.

In response to this Office action, applicant is advised to clear up all of these amendment procedure problems by resubmitting a new claim set with correct claim identifiers and correct amendment markings. The Examiner recommends, for the sake of absolute clarity, canceling claims 1-14 (the highest numbered claim in any claim set) and starting over from new claim 15.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 provide for the use of hydrochloric acid, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 1-12 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd. App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Applicant is advised that claims 1-12 are being examined together here without a restriction requirement because they are currently in "use of" form. Since such claim form is non-statutory as well as indefinite, no restriction is deemed appropriate at this time. If applicant amends the claims to method claims with distinct and active method steps, applicant is hereby given notice that a restriction between a method of treating tumors and a method of providing analgesic relief may be required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 6-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for "use of" hydrochloric acid for the manufacture of a medicament for therapeutic treatment of tumors, does not reasonably provide enablement for the full scope of "curative" treatment of tumors. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The rejected claims read on manufacture of a medicament that provides a cure or curative treatment for tumors, including benign, malignant and metastatic tumors. Such cure or curative treatment is obtained, according to the claimed invention, by the "use of hydrochloric acid."

The state of the art is such that there is no known cure for cancer or other unexplained neoplastic growth, including benign tumors. Treatments are known, but a cure or curative treatment, in the broadest sense of the term, has not yet been achieved in the art. A person treated for cancer or benign tumor is not immune from getting cancer or another type of benign tumor again (since, for example, another benign tumor could grow due to different neoplastic etiology) and there is no known medicament that has such efficacy. While the level of one of ordinary skill in this art is quite high since an

MD or equivalent is needed to treat humans with tumors, the level of unpredictability is extraordinarily high. According to the American Cancer Society, about 1.4 million new cases of cancer in the U.S. were expected in 2006 and over 560,000 Americans are expected to die from cancer in 2006 (Cancer Facts & Figures 2006, pages 1-2). Clearly, there is a high level of unpredictability and lack of prior success that such high numbers of cancer/tumor cases cannot be cured or given "curative treatment" and must eventually lead to such high mortality figures.

Applicant's specification is devoid of any direction or working examples related to curing or providing curative treatment of tumors. Curing or providing curative treatment of tumors encompasses a scope that is far more extensive than providing therapeutically effective treatment of tumors. Given the multiple and distinct etiologies of all the different types of tumors, and in view of the totality of the factors considered here, one skilled in the art would be faced with undue experimentation in order to manufacture a curative treatment with "[t]he use of hydrochloric acid."

For these reasons, the claims are rejected for lacking in adequate enabling support.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6 and 9-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Martucci (US 2003/0035847).

It is noted that Martucci claims the benefit of Provisional application 60/282,026, filed on April 6, 2001, which predates applicant's foreign priority date. A copy of the provision application is attached hereto. All disclosures of Martucci discussed hereinbelow find descriptive support from the provisional application.

Martucci explicitly discloses the use of 3-25 wt% hydrochloric acid in a medicinal substance to treat tumors (see paragraphs 27, 43 (line 6 of the paragraph), and 97-99). Treatment of micro metastasis is disclosed (paragraph 98). Treatment of malignant melanoma is disclosed (Example 18 on page 11). Treatment of benign tumors such as endodermic papilloma (Example 19 on page 11) is disclosed. Treatment of metastatic breast cancer is disclosed (Example 12 on pages 9-10). See also claims 8-98. Alleviating pain from cancer is disclosed (claim 86).

This ground of rejection is directed to a scope of "curative treatment" wherein the "cure" is limited to the treatment of the specific tumor treated, i.e. it is not directed to a scope of cure which is a permanent cure thereafter against other tumors. Given that Martucci unquestionably discloses the "use of" 3-25 wt% hydrochloric acid in the

manufacture of a medicament for the treatment of tumors, the claims are deemed to be anticipated. The specifics of the dependent claim features are disclosed by Martucci, as discussed above. With respect to the "use of" hydrochloric acid for the manufacture of an analgesic for relieving cancerous pain, it is the Examiner's position that a tumor treating medicament such as Martucci would necessarily provide analgesic relief since the pain source, the tumor, is treated or eliminated. Martucci's claim 86 is evidence thereof.

For these reasons, the claims are rejected as being anticipated.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martucci.

Discussion of Martucci's teachings set forth above is incorporated herein by reference. Further, Martucci discloses utilizing the 3-25 wt% hydrochloric acid containing medicament in dose range of 5-1000 drops per day (claim 27).

Claims 1-6 and 9-12 were previously rejected as being anticipated by Martucci. Hence, with respect to these claims there is no patentable difference between the claimed invention and Martucci. Alternatively, even if there were any difference, Martucci's teachings are suggestive of the claimed invention because Martucci teaches treatment of various types of tumors with the "use of" 3-25 wt% hydrochloric acid. The

tumors affected would be treated, which is within a limited scope of "curative" as it pertains to the affected tumors.

With respect to the use of 18 wt% hydrochloric acid and such concentration at a dose of 0.05-5 ml (applicant's claims 7-8), Martucci's use of 5-1000 drops of a medicament containing 3-25 wt% hydrochloric acid is fairly suggestive of applicant's claim features. The ordinary skilled person in the art would have been motivated to select a percentage such as 18 wt% within the 3-25 wt% range and expect tumor treatment, as taught by Martucci. 5-1000 drops are suggestive of 0.05 to 5 ml.

Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the teachings of the cited reference.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martucci in view of Roussel (US 7,041,302).

Discussion of Martucci's disclosure, and its difference with the claimed invention, was fully set forth in the previous ground of rejection under 35 U.S.C. 103(a), and the discussion there is incorporated herein by reference for sake of brevity and clarity. Further, it can be noted that Martucci discloses various modes of administration (paragraphs 84-85).

Roussel adds to Martucci's teaching in disclosing disruption of tumor tissue by direct administration to tumor tissue of a solution of concentrated acid such as hydrochloric acid (column 9, lines 37-40). As an example, Roussel discloses that a 10 M HCl solution (about 36 wt% HCl) administered to a tumor intra-tumorally at a volume of about 100 microliter (about 0.1 ml) can be expected to induce death of about 10-20% of tumor cells (column 9, lines 39-50). See also claims 1 and 3. Adjustment of parameters is disclosed to effect different levels of tumor kills (column 9, lines 50-51).

It is the Examiner's position that Martucci renders all the claims obvious for the reasons fully set forth in the preceding ground of rejection, which reasons are adopted herein. Further, Roussel provides additional motivation that one having ordinary skill in the art would have practiced the "use of hydrochloric acid" for manufacturing a medicament to treat tumors and alleviate cancerous pain. Roussel provides another way in which an acid such as hydrochloric acid can be expected to kill cancer cells. As a result, one having ordinary skill in the art would have been able to vary the concentration and dosage, such as higher volume dose of less concentrated HCl, e.g. 18 wt% HCl, to optimize the cancer cell kill rate for the particular cancer under treatment. As noted previously, the ordinary skilled person in the art would have been motivated to select a percentage such as 18 wt% within Martucci's 3-25 wt% range and expect tumor treatment, as taught by Martucci. Martucci's 5-1000 drops are suggestive of the claimed dose amounts.

Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the teachings of the cited references.

Lastly, it is noted that although this is a 371 application and a certified copy of the foreign priority application is supposed to come from the International Bureau, no such copy is presently of record in this application. Applicant may submit a certified copy for this application, although applicant is not required to do so.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620.** The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Johann Richter, can be reached on **(571)272-0646**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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